

## **REMARKS**

Claims 29-41 and 43 are pending in the application. Claim 29-37 and 39-41 are currently amended.

### **I. Restriction Requirement**

Applicant appreciates Examiner's rejoining of the Groups I-IV claims.

### **II. Drawings**

The drawings submitted on 12/8/03 were otherwise identical to the previous version of drawings contained in the application serial # 09/613,666, except for minor changes such as changes to the line quality as required by the Office during the course of prosecution for the parent application 09/613,666. A new copy of all drawings is being submitted with this paper. Because no changes to any words or symbols have been made, and it would be difficult to show changes in line quality, Applicant is submitting a replacement copy, but not an annotated copy.

### **III. Claim Objections**

Claim 36 is objected to because of informalities. Claim 36 has been amended according to the Examiner's recommendation to correct the typographical error. Applicant appreciates the Examiner's recommendation in making the correction.

### **IV. Claim Rejections--35 U.S.C. §112 Second Paragraph**

Claim 29-32, 37 and 39-41 and their dependent claims are rejected under 35 U.S.C. §112 second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner maintained that the term "yeast derived promoter" is vague and indefinite, Examiner questioned how the promoter is derived from yeast. Applicant would like to draw the Examiner's attention to lines 29-31, page 11 of the Specification as filed, where it was stated that the promoter is preferably isolated from the organism to be transformed as opposed to being synthesized chemically. Thus, the yeast derived promoter as claimed may be isolated from yeast. Methodology for isolation of yeast promoter DNA may be readily found in literature

publicly available at the time the instant Application was filed, for example, in this handbook by Guthrie and Fink, "Guide to yeast genetics and molecular biology. In Methods in Enzymology," Guthrie, C. & Fink, G. R. (1991)(Academic Press, San Diego) **194**:1–932. Applicant is not required to disclose what is well known in the art. Thus, the meaning of "yeast derived promoter" is not vague or indefinite and withdrawal of the rejections is respectfully requested.

**V. Claim Rejections--35 U.S.C. §112 First Paragraph**

Claim 29-41 and 43 are rejected under 35 U.S.C. §112 First Paragraph as failing to comply with the written description requirement. The Examiner maintains that the claims do not provide any structural information with regard to the ratios of amino acids required, and how such ratios would be determined such that it would complement an insufficiency in a predetermined feed source. Claims 29-37 and 39-41 have been newly amended. As amended, the ratio of amino acids in the polypeptide encoded by the construct of Claim 37-41 or expressed by the transformed yeast strains of claim 29-36 are governed by the dietary need of the animal which is in turn controlled by the nature of the animal, the particular feed source selected. The Specification at page 7-8, and again in Example 9 at page 29-31 provide ample showing of how the dietary requirements may be determined.

The instant application, along with what is well known in the art, provides ample teaching by which the composition of the polypeptide can be determined. More particularly, page 7, lines 24-31 of the Specification teaches how a cereal grain may be selected, and how the amount and ratio of amino acids required to be supplemented may be determined. Examples of amino acids requirements by three different species are also provided in the table on Page 8 and again by Example 9 on page 29 of the Specification. The nutritional needs of a given animal and the amino acids content of a given feedstock may be readily determined by consulting standard veterinary and animal science handbooks. Thus, all limitations of Claims 29-41 and 43 as amended are adequately described in the Specification as originally filed, and one of skills in the art would recognize that Applicant was in possession of the invention at the time the instant application was filed. Withdrawal of the rejections under 35 U.S.C. §112 First Paragraph is respectfully requested.

**VI. Claim Rejections--35 U.S.C. §102**

Claim 29, 37 and 43 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,826,957 issued to Nussenzweig et al. ('957 patent). The Examiner interpreted these claims as encompassing ANY transformed yeast cells which expresses a heterologous protein under the control of a yeast derived promoter. Applicant respectfully disagrees. Claims 29, 37 and 43, as amended, are specifically limited to yeast cells or DNA construct or use thereof, that contain a gene encoding a polypeptide with amino acid content of said polypeptide being determined by the desired quantity and ratio of amino acids for dietary requirements of the animal. The desired quantity and ratio of amino acids for dietary requirements of the animal is in turn determined by the grain cereal and the specific nutritional needs of the particular animals. All these limitations are not taught or suggested by the '957 patent and withdrawal of the §102(b) rejection is respectfully requested.

Claim 29-30, 32, 34-37, 39-41 and 43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,337,193 issued to Tully et al. ('193 patent). The Examiner again interpreted the claims as encompassing any yeast strain with any construct that direct the expression of any proteins. Applicant respectfully traverses this rejection because Tully et al does not disclose the claim limitation of determining the amino acid requirement of an animal fed with a particular grain and thus the transformed yeast strain of Tully is distinguishable from the presently claimed yeast strain in the composition of the introduced construct. Withdrawal of the rejections is respectfully requested.

Claim 29-30, 32-34, 36-37 and 43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,985,605 issued to Cheng et al. ('605 patent). For reasons similar to those presented in the previous paragraph, Applicant respectfully traversed this rejection because Cheng et al. lacks teachings on determining the amino acid requirement of an animal fed with a particular grain in order to design the composition of the DNA construct to be introduced into the yeast strain. Withdrawal of the rejection over Cheng is respectfully requested.

Claim 29-30, 32-34, 36-37 and 43 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,985,605 issued to Lei et al.. Applicant noticed that the

Examiner mistakenly cited the same '605 patent with different inventors. Since Lei is not an inventor of U.S. Patent No. 5,985,605, clarification by the Examiner is respectfully requested.


**VII. Claim Rejections--35 U.S.C. §103**

Claim 29-30, 32-34, 36-38 and 43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,985,605 issued to Lei et al. in view of Sikorski et al. (Genetics 122: 19-27, 1989). Again Applicant requests clarification from the Examiner on the Lei reference. Since the identity of the Lei reference can not be ascertained, Applicant has no choice but to defer its response to this obviousness rejection until clarification has been made by the Examiner.

The Commissioner is authorized to charge Deposit Account No. 12-0600 for the required fee for a two-month extension of time.

Respectfully submitted:

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